

In the Claims:

Claims 1-22 (Canceled)

Claim 23 (currently amended): A ~~web-based~~ data processing system for enhancing patient-physician communications by collecting ~~comprehensive~~, structured health information from a patient and organizing and presenting the health information for use by clinicians, the system comprising the following components:

(a) a data processing mechanism programmed to gather health information and relative importance data from patients, the data processing mechanism including an automated interviewing mechanism for conducting a patient interview using a logic-driven, branching ~~menu~~ structure, the patient interview includes a plurality of interview elements:

wherein the interviewing mechanism implements screening questions for the interview element, the screening questions relate to the content of the interview element and determine at least one of clinical relevance, symptoms, current health conditions, and issue importance to the patient;

wherein the interviewing mechanism uses an interview threshold linked to the interview element for controlling execution of the interview element;

wherein the data processing mechanism includes an interview configuration mechanism for overriding a default threshold of the interview element with a modified threshold;

wherein the data processing mechanism uses patient responses for determining at least one of an inquiry scope and an inquiry depth for the patient interview in response to

~~the relative importance data received from the patient; the relative importance data specifying relative importance of each of a plurality of health issues to the patient; the inquiry scope specifying a range of interview topics to be covered, and the inquiry depth specifying a level of detail for a characterization of elicited symptoms;~~

wherein the data processing mechanism is also programmed to analyze, prioritize, and arrange gathered health information for output at least one of printout, and display, so as to provide access and management of health information in a problem-based structure, organized by symptom and/or medical condition;

D1
the data processing mechanism further includes including an interview configuration selection mechanism by which at least one of clinician, a clinical investigator, an administrator, a research coordinator, a physician, a nurse, and a health care professional for designating designate an interview configuration a modified threshold profile for the a patient, set up patient interview schedules, and designate a receiving physician for receiving a patient report corresponding to the patient; and

(b) a patient health information database, coupled to the processing mechanism, for storing gathered health information; and

(c) an Internet server, coupled to the data processing mechanism and to the patient health information database, the Internet server providing problem-based access to current and past health information stored in the patient health information database.

Claim 24 (currently amended): The system of claim 23 wherein a network server is coupled to the data processing mechanism and to the patient health information

database, the server provides access to health information stored in the patient health information database the Internet server encrypts information and provides access to the health information database through a password protected web page.

Claim 25 (currently amended): The system of claim 23 wherein the data processing mechanism is programmed to implement a computerized, patient self-administered interview, each element of the interview corresponds such that the interview is structured using a plurality of modules, each corresponding to a respective subject matter area including at least one of physical symptoms, psychosocial conditions, health behaviors, active (current) and past medical conditions, surgeries, procedures, medications and undesirable reactions to medications, allergies, family history, health-related quality of life, functional status, and activities of daily living, demographics, health care utilization, patient satisfaction assessment, quality of care assessment, and research questionnaire; and

D1

wherein each interview element represents a particular degree of detail, the degree of detail determining the depth of the interview.

Claim 26 (currently amended): The system of claim 23 wherein at least one interview element includes a threshold mechanism that controls whether a given interview element is entered or displayed for the patient; and

wherein thresholds include one of an on-off threshold and a conditional threshold;

~~of the inquiry scope and the inquiry depth for the patient are further defined by the data processing mechanism receiving a selection of an interview configuration profile from at least one of a clinician, a clinical investigator, an administrator, a research coordinator, a physician, a nurse, and a health care professional.~~

Claim 27 (currently amended): The system of claim 23 wherein
the data processing mechanism is programmed to implement a method to configure a patient's interview to clinical, research, quality management, or administrative requirements:

wherein an interview configuration profiles contain a collection of modified thresholds that, at the outset of a patient interview, override default thresholds, populating them with the modified thresholds;

D1
wherein the executed interview reflects at least one of (i) thresholds as modified by the interview configuration profile, (ii) the purpose of the interview; (iii) patient responses, and (iv) the potential medical relevance or urgency, as assessed by program logic; and

wherein the configuration selection mechanism allows detailed questioning about symptoms or issues of relative importance as judged by the patient, severity, recent activity, or clinical relevance that meet specified criteria, while allowing limited or no questioning regarding topics of lower clinical relevance.

the processing mechanism matches a specific interview configuration profile to a patient at the time the patient is scheduled for a health care appointment.

Claim 28 (currently amended): The system of claim 27 23 wherein
the data processing mechanism matches a specific interview configuration profile to a
specific patient at least one of a clinician, a clinical investigator, an administrator, a
research coordinator, a physician, a nurse, and a health care professional match a specific
interview configuration profile to a patient at the time the patient is scheduled for a health
care appointment.

D1
Claim 29 (currently amended): The system of claim 23 25 wherein
wherein the screening questions are adapted to the context of the specific
interview element, probing for positive responses, while also ascertaining whether the
issues are clinically relevant;
wherein clinical relevance is defined as at least one of the importance to the
patient, the occurrence of a symptom in the recent past (as compared to the remote past),
medical importance as judged by expert physician opinion, a troublesome or recently
active medical condition, a distressing psychosocial issue, and issues that cause limitation
in function or quality of life;

wherein related physical symptoms are grouped together and an initial screening
question is asked about at least one of the relative importance to the patient, the severity,
and the time profile (current vs. past) of that symptom group; and
wherein more detailed questions regarding individual symptoms are asked only
for groups of symptoms that pass the threshold as set by the interview configuration

~~profile each of the plurality of modules includes one or more screening questions that cover topics relevant for that module.~~

Claims 30-31 (canceled)

Claim 32 (previously presented): The system of claim 29 wherein the processing mechanism is programmed to include a patient viewpoint module for presenting one or more questions to the patient during the interview establish an interview purpose from the patient's point of view, wherein the questions include at least one of a change in the patient's established symptoms, development of new symptoms, problems with medications, obtaining testing results, clarification of questions, and referrals from another clinic or clinician.

Claim 33 (previously presented): The system of claim 23 wherein the processing mechanism is programmed to gather health information related to multiple distinct or overlapping symptoms; and wherein no previous diagnosis is required for system use.

Claims 34-35 (canceled)

Claim 36 (currently amended): The system of claim 23 wherein the processing mechanism further comprises a mechanism for obtaining a history of and characterization of multiple symptoms, regardless of whether they are discrete, separate medical

conditions, or overlapping and related, ~~reflecting linkage to common mechanisms or the same underlying medical condition:~~

- (a) wherein potential associations between symptoms are identified based upon clinical experience;
- (b) wherein, after ascertaining from the patient the presence of more than one symptom in an association of symptoms, an interview question is asked about which symptoms seem related, either by coming and going come and go together in the same time pattern or in response to ~~the same group of~~ precipitating and relieving factors, ~~thereby establishing an instance of an association;~~
- (c) wherein subsequent interview questions characterizing the associated symptoms are combined, thereby reducing the time and redundancy of the interview; and
- (d) wherein the risk of confusing the patient is reduced by detecting relations between symptoms when they exist or allowing symptoms to stand as independent when no association is identified; and
- (e) wherein data are gathered to help establish whether the development of new symptoms or the change in status of established symptoms reflects a change in disease condition, side effects of medication, development of a related condition, or development of an unrelated condition.

Claim 37 (currently amended): The system of claim 23 wherein the processing mechanism is programmed to conduct an interview that integrates questions about physical symptoms biomedical and psychosocial conditions elements,

wherein questions are asked about common psychological conditions, such as one or more of depression, anxiety, panic disorder, poorly tolerated stress, and post-traumatic stress disorder

(a) ~~such that the interview captures scaled responses for at least one of frequency or distress, and bother associated with the symptom, rather than categorical (yes/no) responses;~~

(b) ~~such that the health information is used as the basis for a personal interview by a clinician to establish psychiatric diagnosis by means of established criteria (DSM-IV, Diagnostic and Statistical Manual for Psychiatric Disease);~~

(c) ~~wherein biopsychosocial health information is presented to a clinician using either a printed report format or a display presentation presented using at least one of a printer and a visual display device; and~~

(d) ~~wherein the data presentation ranks patient symptoms or positive responses by criteria related to diagnostic thresholds.~~

Claim 38 (currently amended): The system of claim 23 37, wherein patient data regarding the severity of physical symptoms are used to calculate a severity index that can be used for diagnostic purposes;

wherein different levels of severity are assigned logarithmic values, such as mild equals 1, moderate equals 10, severe equals 100, and very severe equals 1000; and
wherein symptoms from a similar region of the body are grouped together to facilitate interpretation by a physician

*col 16,
lines
55-58*

(a) ~~wherein the data presentation includes comments and instructions regarding interpretations or subsequent questions;~~

(b) ~~wherein data presentation includes scores for symptoms or conditions that can be used for diagnostic purposes;~~

(c) ~~wherein clinicians change patient inputted data and recalculate the scores;~~

(d) ~~wherein clinicians respond to additional interview questions and recalculate scores;~~

(e) ~~wherein the interview is constructed in modules that cover a plurality of disorders, thereby allowing the interview to cover any medical or psychosocial psychiatric disorders; and~~

(f) ~~wherein the interview process prepares the patient for a personal interview with the clinician.~~

D|
Claim 39 (currently amended): The system of claim 23 wherein the processing mechanism further comprises a mechanism for gathering patient data regarding their health-related quality of life (HRQL) data, which include at least one of the patient's functional status regarding physical activities, ability to work, social activities ~~be active~~ socially, participation ~~participate~~ in relationships, performance of ~~perform~~ activities of daily living, management of personal hygiene, ~~and care, and tolerance for~~ compromised HRQL relating to specific medical conditions:

(a) wherein HRQL data will be used for one or ~~of~~ more of the following: clinical care, research purposes, ~~and~~ or quality management;

(b) wherein initial screening questions will first establish potential problem areas, which and then prompt more detailed questions where warranted;

(c) wherein an integrated, general question set will characterize HRQL impact of issues shared among common medical and psychosocial disorders; and

(d) (e) wherein, when one of a specified specific symptoms, or medical conditions, and psychosocial conditions are identified, more specific HRQL question sets will be selectively asked applied to ascertain detailed data regarding the impact of specific conditions on HRQL issues;

(d) wherein, more specific questioning pursue issues common to several medical and psychosocial conditions, such as impact of disease on self image, social life, sexual relations, functioning at work, and ability to engage in hobbies;

(e) wherein wording parameters are used to substitute wordings specific for a given condition in a given patient, thereby allowing a generic approach to be automatically applied to specific conditions; and thereby providing specific measures of HRQL that will be useful for establishing change in patient status as a result of disease progression or treatment.

Claim 40 (previously presented): The system of claim 23 wherein the processing mechanism further comprises a mechanism for conducting interview sessions to run in a single session, or to be suspended and completed at a subsequent session; wherein residual modules that were not conducted can be completed at a subsequent session.

Claim 41 (currently amended): The system of claim 23, wherein the data processing mechanism generates a patient report processing mechanism further comprises a mechanism for supporting a subsequent follow-up interview for at least one of clinical care, research, or quality management purposes.

Claim 42 (currently amended): The system of claim 23 41 wherein the processing mechanism supports subsequent follow-up interviews: — *any interview*

(a) the processing mechanism gathers at least one of interim change data specifying a change in established symptoms, new symptom data specifying new symptoms, status change data specifying a change in status, and available information data specifying a change in available information regarding aspects of an individual's health condition and repeat presentation of;

(b) the processing mechanism causes predetermined interview questions to be repeated, thereby gathering a matching set for comparison with previous data for clinical, research, or quality management purposes.

Claim 43 (currently amended): The system of claim 42 wherein:

(a) interview questions related to symptoms active at a previous interview are presented to the patient, the interview questions inquiring about status (worse, no change, better, not sure);

(b) a summary of active and past medical conditions, surgical history, and family history is presented to ascertain whether any new developments have occurred or whether the patient is aware of information not reported previously last time; and

(c) health-related quality of life questions are asked to determine change in the patients functional status and impact of health conditions, thereby ~~providing a sound basis for assessing change for the purposes of clinical care, clinical research, or assessment of the quality of care.~~

Claim 44 (currently amended): The system of claim 37 wherein:

(a) current patient information is accessed from the database of patient information in a by problem-oriented fashion area, wherein problems are symptoms and symptom, or medical conditions condition;

(b) the data are presentation is presented according to medical problems;

(c) the data presentation organizes problems orders data by one ore more of relative importance to the patient priority, currency, and/or previously-assigned physician ranking, such that most important issues can be identified and separated from low priority or past issues;

(d) names of medical problems are modifiable, and new names can be created;

(e) a hierarchy of medical problems (including both symptoms and medical conditions) can be changed;

(f) symptoms and problems can be associated and disassociated from problems;

and

(g) ~~(f)~~ notes can be entered ~~comments are accepted~~ related to patient history, physical examination, assessment of etiology, and plans for treatment and follow-up.

Claim 45 (currently amended): The system of claim 44 wherein the data presentation ~~is represented in a "SOAP" format which includes subjective or patient reported symptoms, Objective or clinician observations, Assessment, and Plans;~~ ~~wherein the data presentation~~ can be electronically edited and signed to thereby create a clinical note, as an official consultation report or progress note for the patient; and

wherein an audit trail is provided for changes in clinical notes; and ~~wherein before electronic signature~~ and clinical notes are frozen for editing after signature.

Claim 46 (previously presented): The system of claim 23 further comprising a display mechanism for managing patient information by displaying current or past health information in a ~~medical~~ problem-oriented fashion, thereby allowing past and current health information for a given medical problem to be identified and viewed.

Claim 47 (previously presented): The system of claim 46: wherein a template function is provided for entering health information regarding physical examination, assessment, and plans;

wherein a menu of treatment plans for each of a plurality of predefined health problems are established by a consensus of clinical experts or review of medical literature; and

wherein an action or actions to be taken from a list of commonly taken clinician actions enumerated in treatment plans is/are selected.

Claim 48 (previously presented): The system of claim 47:

wherein selected treatment options summarized in treatment plans are printed in a list or directly linked to generation of orders by means of an electronic medical record or order-execution system.

Claim 49 (currently amended): The system of claim 23 wherein the processing

mechanism is programmed to schedule patient contacts, physician communication, and patient appointments;

wherein patient contact information is gathered at the time the interview is scheduled, including at least one of patient email address, telephone phone number, or address for regular mail;

wherein select interview configurations are matched to patients; and

wherein interview modules are selected to be run or repeated at the next session;

~~and wherein a pre-formatted or free text messages is generated, and a patient contact is activated including at least one of: a clinic visit or testing appointment~~

~~schedule, a request to perform computer interviews or additional interview modules, test results, instructions, and reminders to do or complete follow-up electronic interviews.~~

Claim 50 (currently amended): The system of claim 23 further comprising a mechanism for integrating administrative functions relating to documentation of health problem management, and generating a report based on patient-inputted or physician-inputted data, such that clinicians accept a provisionally-assigned health problem name or re-select problem names from a pre-defined list of established health problem names;

(a) wherein, when a health problem name is selected, matching automatically occurs to a standard ICD-9 or newer diagnostic and billing code; and

D |
(b) wherein health information regarding active problems that were attended during a clinic session are used to generate and update a health problem list, pursuant to specifications promulgated by an accrediting organization the Joint Commission on Accreditation of Hospital Organization (JCAHO).

Claim 51 (currently amended): The system of claim 50 wherein health information regarding active problems that were attended during a clinic session are used to generate an encounter form summarizing such problems that can be used for billing purposes;

wherein components of the interview and data presentation are analyzed and categorized with respect to established criteria to identify appropriate coding for the level of services offered for billing purposes;

~~wherein a clinical note is generated which includes reference to expense coding for billing purposes and documentation for that coding; and wherein data regarding such documentation for billing purposes are available in the health information database for separate analysis.~~

Claim 52 (previously presented): The system of claim 23 wherein the processing mechanism is programmed to implement a patient interview:

- (a) wherein a non-response to a question is not offered as an option and responses are required before it is possible to proceed to the next question; and
- (b) wherein responses for each question are designed to include an appropriate response for patients.

Claim 53 (currently amended): The system of claim 23 further comprising a mechanism for implementing quality management that includes quality assessment and improvement based upon patient-inputted data;

- (a) wherein the quality management is based upon patient responses regarding issues including at least one of symptoms, health-related quality of life, patient understanding of a health condition, patient health attitudes and behaviors, patient willingness to change health behaviors, patient perceptions of communication with a clinician, patient observation about the health care they are receiving, patient understanding of what to expect and what to watch out for, patient understanding of a

treatment they are receiving, patient understanding of medications they should be using, and patient compliance with medication and with treatment.

Claim 54 (currently amended): The system of claim 53 wherein quality improvement is focused on either preventive health or disease status and treatment; wherein patient-derived quality data are integrated into the clinical report given to the physician so that action can be taken during the upcoming session or subsequently to correct medical problems and improve care; wherein such quality improvement data can be presented to a clinician with suggestions regarding appropriate care; and wherein an interview regarding quality of care is conducted at one or more of the following times: during the pre-visit interview, during a exit interview at the time of the session, during a follow-up interview where patients are sent ~~a an email~~ reminder, and by means of questions inserted into a revisit interview.

Claim 55 (currently amended): The system of claim 23 wherein the processing mechanism is programmed to assess patient satisfaction with medical care, such that interview questions probe issues including ~~at least one of the~~ patient's satisfaction with a physician or a clinic encounter, waiting times for an appointment, waiting times to see a clinician, access to care, ~~and~~ courtesy with which the patient is treated, and whether the patient felt their concerns were heard and understood by the clinician.

Claim 56 (currently amended): The system of claim 55 wherein the interview questions are asked at one or more of the following times: during a pre-visit interview, during an exit interview at the time of the session, during a follow-up interview where patients are sent a ~~an~~ ~~email~~ reminder, and by means of questions inserted into a revisit interview.

Claim 57 (currently amended): The system of claim 23 wherein the processing mechanism further comprises a mechanism for supporting and facilitating clinical research in practice settings, as well as in research clinics, wherein the processing mechanism:

(a) automates patient recruitment for research trials;

(b) queries patients to determine whether they would like to be informed regarding research studies for which they are eligible;

(c) receives eligibility requirements for research studies and uses system logic to identify when patient responses regarding one of symptoms and ~~or~~ medical conditions ~~or~~ patient demographies, such as age ~~or~~ gender, that may qualify the patient for a research study; and

(d) informs one of patient and research coordinator of studies for which ~~they are~~ the patient is eligible by computerized notification; and

(e) electronically forwards to patients a specific description of the study and asks if ~~they would like their contact information forwarded to investigators, and if they want contact information for investigators.~~

Claim 58 (currently amended): The system of claim 23 wherein the processing mechanism is programmed to aid clinical research, such that:

(a) data regarding one of patient symptom assessment, patient health-related quality of life assessment, clinical outcomes, and physician treatment process, and resource utilization gathered in the course of care using the system populates the health information database and are used for research purposes; and

(b) the system is used for clinical trials to facilitate capture of patient assessment data regarding at least one of physical symptoms, biomedical and psychosocial issues, data regarding physician treatment process, and follow-up follow-up data for regarding treatment process and patient outcomes.

Claim 59 (previously presented): The system of claim 23 wherein the processing mechanism is programmed to:

- (a) elicit and structure information for a corporate health service; and
- (b) track patient response over time.

Claim 60 (new): The system of claim 26, wherein said conditional threshold includes a threshold that depends on one of patient responses regarding symptoms, medical conditions, health history demographics; and interview process data; and
wherein said conditional threshold enables complex assessment of patient responses.

Claim 61 (new): The system of claim 23, wherein said interview threshold controls the scope of the interview by controlling access to interview elements of the interview.

Claim 62 (new): The system of claim 23, wherein said interview threshold determines the depth of the interview by controlling access to more detailed questions that further characterize patient responses.

Claim 63 (new): The system of claim 41, wherein the patient report includes a summarization of the gathered patient data;

D2
wherein programming logic is used to flag potentially critical findings using criteria established by one of clinical experience and expert consensus; wherein severity scores for physical symptoms are summarized, ranked by one of relative importance to the patient and severity score; and wherein scores reflecting the severity of psychosocial conditions are listed; and wherein scores for quality of life assessment are listed.